specification and specifically at page 24, line 4 through page 25, line 6. Therefore, the foregoing amendments are supported by the specification and do not introduce new matter to the specification.

Rejection Pursuant to 35 U.S.C. §112, First Paragraph:

Claims 5-7, 21-31 and 33-36 prior to amendment, were rejected pursuant to 35 U.S.C. §112, First Paragraph as not being sufficiently commensurate in scope with respect to the teaching of the specification and that the ordinarily skilled artisan would not be able to practice the present invention *in vivo* without undue experimentation (Office Action at Page 8). However, the Office Action indicated that the specification is enabling of claims directed to the use of micro-calpain inhibitors in applications that did not require their administration *in vivo*. At page 2 of the Office Action, the Examiner states:

> . . . the specification, while enabling for an *in vitro* method of increasing the infectivity of a cell to a viral vector with a micro-calpain inhibitor, does not reasonably provide enablement for an *in vivo* method of increasing the infectivity of a cell to a viral vector by treatment of the cell with a micro-calpain inhibitor.

The entire balance of the Office Action focuses on the alleged non-enablement of the *in vivo* practice of the present invention.

Although the Applicants disagree with this conclusion for reasons of record, in order to expedite prosecution of this application, the Applicants have amended the scope of the claims of the present application to exclude *in vivo* applications. The Applicants have cancelled this subject matter without prejudice and expressly reserve the right to continue prosecution of this subject matter in a continuation application. Applicants believe that the foregoing amendments obviate the rejection pursuant to 35 U.S.C. §112, first paragraph and respectfully request that this ground of rejection be withdrawn.

CONCLUSION

The Applicants believe that the foregoing Amendments are commensurate with the scope of what the Examiner has indicated to be allowable subject matter in this application. Therefore, the Applicants believe that the pending claims, as amended are in condition for allowance. Consequently, the Applicants respectfully request that this pending claims in this application be granted favorable consideration and this application passed to issuance without further delay.

If the Examiner believes that an interview would expedite the prosecution of this application, the Applicants' attorney would welcome the opportunity to discuss this application further with the Examiner by telephone to resolve any remaining issues.

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Respectfully submitted,

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CLEAN COPY OF CLAIMS AS AMENDED

5. A method of increasing the infectivity of a cell to a viral vector by treatment of the cell with a micro-calpain inhibitor wherein said method is practiced *in vitro* or *ex vivo*.

6. The method of claim 5 wherein said viral vector is an adenoviral vector.

7. The method of claim 6 wherein the micro-calpain inhibitor is calpain inhibitor 1.

21. The method of claim 6 wherein said adenoviral vector is replication deficient.

22. The method of claim 21 wherein said replication deficient adenoviral vector encodes a therapeutic transgene.

23. The method of claim 22 where said transgene is selected from the group consisting of cytostatic genes and pro-apoptotic genes.

24. The method of claim 23 wherein the gene is a cytostatic gene.

25. The method of claim 24 wherein the gene is the p21 gene.

26. The method of claim 23 wherein the gene is a pro-apoptotic gene.

27. The method of claim 26 wherein the gene is p53.

28. The method of claim 5 wherein the vector is replication competent.

29. The method of claim 28 wherein the replication competent vector is a conditionally replicating viral vector.

30. The method of claim 29 wherein the conditionally replicating viral vector further comprises an expression cassette which expresses a pro-apoptotic gene.

31. The method of claim 30 wherein the pro-apoptotic gene is the E3-11.6K gene.

32. The method of claim 31 wherein the viral vector is a replication deficient adenoviral vector and the cell is a producer cell capable of complementing the deleted functions of the replication deficient adenoviral vector.

33. The method of claim 33 wherein the replication deficient adenoviral vector lacks a functional E1 region and the producer cell is a 293 cell.

34. The method of claim 32 wherein said *in vitro* practice of the method is in a process to purge tumor cells from a stem cell product by exposing said stem cell product to a calpain inhibitor prior to the administration of a viral vector.

35. The method of claim 35 wherein said viral vector is an adenoviral vector that encodes and expresses the p53 tumor suppressor gene.

MARKED COPY OF CLAIMS TO SHOW AMENDMENTS

5. A method of increasing the infectivity of a cell to a viral vector by treatment of the cell with a micro-calpain inhibitor wherein said method is practiced *in vitro* or *ex vivo*.

6. The method of claim 5 wherein said viral vector is an adenoviral vector.

7. The method of claim 6 wherein the micro-calpain inhibitor is calpain inhibitor 1.

21. The method of claim 6 wherein said adenoviral vector is replication deficient.

22. The method of claim 21 wherein said replication deficient adenoviral vector encodes a therapeutic transgene.

23. The method of claim 22 where said transgene is selected from the group consisting of cytostatic genes and pro-apoptotic genes.

24. The method of claim 23 wherein the gene is a cytostatic gene.

25. The method of claim 24 wherein the gene is the p21 gene.

26. The method of claim 23 wherein the gene is a pro-apoptotic gene.

27. The method of claim 26 wherein the gene is p53.

28. The method of claim 5 wherein the vector is replication competent.

29. The method of claim 28 wherein the replication competent vector is a conditionally replicating viral vector.

30. The method of claim 29 wherein the conditionally replicating viral vector further comprises an expression cassette which expresses a pro-apoptotic gene.

31. The method of claim 30 wherein the pro-apoptotic gene is the E3-11.6K gene.

~~32. The method of claim 5 wherein the method is practiced *in vitro.*~~

33. The method of claim ~~32~~ 31 wherein the viral vector is a replication deficient adenoviral vector and the cell is a producer cell capable of complementing the deleted functions of the replication deficient adenoviral vector.

34. The method of claim 33 wherein the replication deficient adenoviral vector lacks a functional E1 region and the producer cell is a 293 cell.

35. The method of claim 32 wherein said *in vitro* practice of the method is in a process to purge tumor cells from a stem cell product by exposing said stem cell product to a calpain inhibitor prior to the administration of a viral vector.

36. The method of claim 35 wherein said viral vector is an adenoviral vector that encodes and expresses the p53 tumor suppressor gene.